IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of: Charles Edward Baumgartner et al. | § | Group Art Unit: | 3737 |
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| | § | Confirmation No.: | 6500 |
| Serial No. 10/814,830 | § | | |
| Filed: March 31, 2004 | § | Examiner: | Ramirez, John Fernando |
| | § | | |
| For: System and Method for Power Management in an Ultrasound System | § | Atty. Docket: | 134678-1 GERD:0086/SWA |
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| February 19, 2010 | /Tait R. Swanson/ |
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| Date | Tait R. Swanson<br>Reg. No. 48,226 |

**RESPONSE TO NOTICE OF NON-COMPLIANT APPEAL BRIEF, AND SUPPLEMENTAL APPEAL BRIEF PURSUANT TO 37 C.F.R. §§ 41.31 AND 41.37**

This Supplemental Appeal Brief is being filed in furtherance to the Pre-Appeal Brief Request for Review and the Notice of Appeal mailed on November 13, 2006, and received by the Patent Office on November 16, 2007, the Notice of Panel Decision from Pre-Appeal Brief Review mailed on February 12, 2007, the original Appeal Brief mailed on April 10, 2007, and received by the Patent Office on April 13, 2007, and a Notice of Non-Compliant Appeal Brief mailed on January 22, 2010 (hereinafter "the Notice"). In the Notice, the Examiner indicated that claims 18 and 23 as listed in the original Appeal Brief were inconsistent with the Amendment filed on April 10, 2006. Accordingly, the Appellants hereby correct the listing of claims to indicate the correct text as set forth in the Amendment filed on April 10, 2006. In particular, the Appellants stress that claims 18 and 23 are now consistent with the Amendment filed on April 10, 2006. In view of these corrections, the Appellants submit that the present Supplemental Appeal Brief is now compliant.

1. **REAL PARTY IN INTEREST**

The real party in interest is General Electric Company, which is the Assignee of the above-referenced application by virtue of the Assignment recorded at reel 015173, frame 0497, and recorded on March 31, 2004. General Electric Company, the Assignee of the above-referenced application as evidenced by the documents mentioned above, will be directly affected by the Board's decision in the pending appeal.

2. **RELATED APPEALS AND INTERFERENCES**

Appellants are unaware of any other appeals or interferences related to this appeal. The undersigned is Appellants' legal representative in this appeal.

3. **STATUS OF CLAIMS**

Claims 1, 3-21, and 23-24 are currently pending, are currently under final rejection, and, thus, are the subject of this appeal. Claims 2 and 22 were previously cancelled and are not subject to this appeal.

4. **STATUS OF AMENDMENTS**

In response to the Final Office Action mailed on June 23, 2006, the Appellants amended claim 18 to correct a spelling error as follows: "~~non-ultransonicaly~~ non-ultrasonically." *See* Amendment filed on August 23, 2006. In the Advisory Action mailed on October 10, 2006, the Examiner did not enter the foregoing amendment. In the Notice of Non-Compliant Appeal Brief mailed on January 22, 2010, the Examiner indicated that claims 18 and 23 as listed in the Appeal Brief were inconsistent with the Amendment filed on April 10, 2006. Upon further review, the Appellants determined that the spelling error of claim 18 did not exist in the Amendment filed on April 10, 2006, and thus entry of the Amendment filed on August 23, 2006 is now moot.

## 5. SUMMARY OF CLAIMED SUBJECT MATTER

The invention relates generally to imaging systems and, more specifically, to a method and apparatus for controlling power and heat generated by medical ultrasound imaging probes based on sensed contact with a subject. *See* Application, paragraph [0001]. The present application contains five independent claims, namely claims 1, 9, 15, 18, and 23, all of which have been improperly rejected and, thus, subject to this appeal. The subject matter of the independent claims is summarized below.

With regard to the embodiment of the invention set forth in independent claim 1, discussions of the recited features of claim 1 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with the present invention relates to an ultrasound system (*e.g.*, 10) having an ultrasound probe (*e.g.*, 12, 58). *See, e.g.*, Application, FIGS. 1 and 2, paragraphs [0011] and [0024]. The ultrasound probe (*e.g.*, 12, 58) includes an ultrasonic transducer (*e.g.*, 18), and a physical sensor (*e.g.*, 20, 81, 82) adapted to sense engagement with a subject (*e.g.*, 16) to be scanned by the ultrasonic transducer (*e.g.*, 18), wherein the physical sensor (*e.g.*, 20, 81, 82) is independent from the ultransonic transducer (*e.g.*, 18). *See, e.g.*, Application, FIGS. 1 and 3, paragraphs [0011], [0012], [0015], [0017], [0031], and [0032]. The ultrasound system (*e.g.*, 10) also includes a control system (*e.g.*, 14) coupled to the ultrasound probe (*e.g.*, 12, 58) and configured to control power modes of the ultrasound probe (*e.g.*, 12, 58) based on feedback from the physical sensor (*e.g.*, 20, 81, 82). *See id.*

With regard to the embodiment of the invention set forth in independent claim 9, discussions of the recited features of claim 9 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with the present invention relates to a method for controlling (*e.g.*, 14) heat in an ultrasound system (*e.g.*, 10). *See, e.g.*, Application, FIGS. 1 and 3, paragraphs [0011], [0012], [0015], [0017], [0031], and [0032]. The method includes physically sensing engagement of an ultrasound module (*e.g.*, 12, 58) with a subject (*e.g.*, 16) using a non-

ultrasonic sensor (*e.g.*, 20, 81, 82). *See id.* The method also includes switching power modes (*e.g.*, 100, 102) of the ultrasound module (*e.g.*, 12, 58) based on the sensed engagement. *See id.*

With regard to the embodiment of the invention set forth in independent claim 15, discussions of the recited features of claim 15 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with the present invention relates to an ultrasound system (*e.g.*, 10). *See, e.g.*, Application, FIGS. 1 and 2, paragraphs [0011] and [0024]. The system (*e.g.*, 10) includes a hand holdable ultrasound probe (*e.g.*, 12, 58), which includes an ultrasonic transducer (*e.g.*, 18) configured to scan a subject (*e.g.*, 16), and a non-ultrasonic sensing element (*e.g.*, 20, 81, 82) configured to detect physical proximity of the hand holdable ultrasound probe (*e.g.*, 12, 58) relative to the subject (*e.g.*, 16). *See, e.g.*, Application, FIGS. 1 and 3, paragraphs [0011], [0012], [0015], [0017], [0031], and [0032]. The system (*e.g.*, 10) also includes a control system (*e.g.*, 14) coupled to the hand holdable ultrasound probe (*e.g.*, 12, 58), wherein the control system (*e.g.*, 14) is configured to switch the ultrasound probe (*e.g.*, 12, 58) between a plurality of power modes (*e.g.*, 100, 102) based on feedback from the sensing element (*e.g.*, 20, 81, 82). *See id.*

With regard to the embodiment of the invention set forth in independent claim 18, discussions of the recited features of claim 18 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with the present invention relates to a method of manufacture, which includes providing an ultrasound unit (*e.g.*, 12, 58) having an ultrasound transducer (*e.g.*, 18) to scan a subject (*e.g.*, 16) and a physical sensor (*e.g.*, 20, 81, 82) to non-ultransonicaly detect proximity of a subject (*e.g.*, 16) relative to the ultrasound unit (*e.g.*, 12, 58). *See, e.g.*, Application, FIGS. 1 and 3, paragraphs [0011], [0012], [0015], [0017], [0031], and [0032]. The method also includes providing a control system (*e.g.*, 14) to change power levels (*e.g.*, 100, 102) of the ultrasound unit (*e.g.*, 12, 58) based on the feedback from the physical sensor (*e.g.*, 20, 81, 82). *See id.*

With regard to the embodiment of the invention set forth in independent claim 23, discussions of the recited features of claim 23 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with the present invention relates to an ultrasound system (*e.g.*, 10). *See, e.g.*, Application, FIGS. 1 and 2, paragraphs [0011] and [0024]. The system (*e.g.*, 10) includes means (*e.g.*, 20, 81, 82) for sensing non-ultrasonic signals to detect physically detecting proximity of an ultrasound module (*e.g.*, 12, 58) relative to a subject (*e.g.*, 16) to be scanned by ultrasonic transducers (*e.g.*, 18) of the ultrasound module (*e.g.*, 12, 58). *See, e.g.*, Application, FIGS. 1 and 3, paragraphs [0011], [0012], [0015], [0017], [0031], and [0032]. The system (*e.g.*, 10) also includes means (*e.g.*, 14) for switching power modes (*e.g.*, 100, 102) of the ultrasound probe (*e.g.*, 12, 58) based on proximity feedback from the means (*e.g.*, 20, 81, 82) for sensing. *See id.*

## 6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

**First Ground of Rejection for Review on Appeal:**

Appellants respectfully urge the Board to review and reverse the Examiner's first ground of rejection in which the Examiner improperly rejected claims 1, 3, 7, 9, 12, 14-15, 17-18, 21 and 23 under 35 U.S.C. § 103(a) as unpatentable over Emery (U.S. Patent No. 6,610,001, hereinafter, "Emery").

**Second Ground of Rejection for Review on Appeal:**

Appellants respectfully urge the Board to review and reverse the Examiner's second ground of rejection in which the Examiner improperly rejected claims 4 and 19 under 35 U.S.C. § 103(a) as unpatentable over Emery in view of Chiang et al. (U.S. Patent No. 5,957,846, hereinafter, "Chiang").

**Third Ground of Rejection for Review on Appeal:**

Appellants respectfully urge the Board to review and reverse the Examiner's third ground of rejection in which the Examiner improperly rejected claims 5-6, 20, and 24 under 35 U.S.C. § 103(a) as unpatentable over Emery in view of Akisada et al. (U.S. Patent No. 6,183,426, hereinafter, "Akisada").

**Fourth Ground of Rejection for Review on Appeal:**

Appellants respectfully urge the Board to review and reverse the Examiner's fourth ground of rejection in which the Examiner improperly rejected claims 8, 10-11, 13 and 16 under 35 U.S.C. § 103(a) as unpatentable over Emery in view of Whitney et al. (U.S. Patent No. 5,396,891, hereinafter, "Whitney").

## 7. ARGUMENT

**First Ground of Rejection:**

The Examiner improperly rejected claims 1, 3, 7, 9, 12, 14-15, 17-18, 21 and 23 under 35 U.S.C. § 103(a) as unpatentable over Emery (U.S. Patent No. 6,610,001, hereinafter, "Emery"). Because this rejection is clearly and directly contrary to previous binding decisions of the Board, as well as the binding precedent of the Federal Circuit, Appellants respectfully traverse this rejection.

***Legal Precedent***

The pending claims must be given an interpretation that is reasonable and consistent with the *specification*. *See In re Prater*, 415 F.2d 1393, 1404-05, 162 U.S.P.Q. 541, 550-51 (C.C.P.A. 1969) (emphasis added); *see also In re Morris,* 127 F.3d 1048, 1054-55, 44 U.S.P.Q.2d 1023, 1027-28 (Fed. Cir. 1997); *see also* M.P.E.P. §§ 608.01(o) and 2111. Indeed, the specification is "the primary basis for construing the claims." *See Phillips v. AWH Corp.*, No. 03-1269, -1286, at 13-16 (Fed. Cir. July 12, 2005) (*en banc*). One should rely *heavily* on the written description for guidance as to the meaning of the claims. *See id.*

Interpretation of the claims must also be consistent with the interpretation that *one of ordinary skill in the art* would reach. *See In re Cortright*, 165 F.3d 1353, 1359, 49 U.S.P.Q.2d 1464, 1468 (Fed. Cir. 1999); M.P.E.P.§2111. "The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." *See Collegenet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 75 U.S.P.Q.2d 1733, 1738 (Fed. Cir. 2005) (quoting *Phillips v. AWH Corp.*, 75 U.S.P.Q.2d 1321, 1326). The Federal Circuit has made clear that derivation of a claim term must be based on "usage in the ordinary and accustomed meaning of the words amongst artisans of ordinary skill in the relevant art." *See id.*

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d. 1430 (Fed. Cir. 1990). Accordingly, to establish a *prima facie* case, the Examiner must not only show that the combination includes *all* of the claimed elements, but also a convincing line of reason as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985). The Examiner must provide objective evidence, rather than subjective belief and unknown authority, of the requisite motivation or suggestion to combine or modify the cited references. *In re Lee*, 61 U.S.P.Q.2d. 1430 (Fed. Cir. 2002). Moreover, a statement that the proposed modification would have been "'well within the ordinary skill of the art'" based on individual knowledge of the claimed elements cannot be relied upon to establish a *prima facie* case of obviousness without some *objective reason to combine* the teachings of the references. *Ex parte Levengood*, 28 U.S.P.Q.2d

1300 (Bd. Pat. App. & Inter. 1993); *In re Kotzab*, 217 F.3d 1365, 1371, 55 U.S.P.Q.2d. 1313, 1318 (Fed. Cir. 2000); *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 U.S.P.Q.2d. 1161 (Fed. Cir. 1999).

When prior art references require a selected combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988). One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). The Federal Circuit has warned that the Examiner must not, "fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *In re Dembiczak*, F.3d 994, 999, 50 U.S.P.Q.2d 52 (Fed. Cir. 1999) (quoting *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983)).

It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983); M.P.E.P.§2145. Moreover, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959); *see* M.P.E.P.§2143.01(VI). If the proposed modification or combination would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); *see* M.P.E.P.§2143.01(V).

In order to rely on equivalence as a rational supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's

disclosure or the mere fact that the components at issue are functional or mechanical equivalents. *In re Ruff*, 256 F.2d 590, 118 U.S.P.Q. 340 (CCPA 1958); *see also* M.P.E.P. §2144.06.

***Deficiencies of Emory***

On a preliminary note, the Examiner has acknowledged that Emery "does not explicitly state that these independent physical sensors detect 'engagement with the subject' as called for in the claim to the degree of inherency necessary for anticipation." Final Office Action, page 3. In formulating the rejection under Section 103(a), the Examiner stated that:

> [I]t would have been inherently obvious to use at least the tissue reflectivity sensor to sense active engagement with the subject. In effect this is tantamount to the distance (proximity) sensor which applicants list in specification para [0015] as a category of physical sensor.

Final Office Action, page 3. This unsupported conclusion is no substitute for the requisite teaching or suggestion in the prior art to modify the device disclosed in Emery. Such a teaching or suggestion is necessary to support a *prima facie* case of obviousness under Section 103. *See In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). Accordingly, Appellants respectfully submit that independent claims 1, 9, 15, 18 and 23 and the claims depending therefrom are allowable and respectfully request the Examiner to withdraw the rejections.

***Independent Claim 1***

Independent claim 1 recites "an ultrasound probe, comprising an ultrasonic transducer; and a physical sensor adapted to sense *engagement* with a subject *to be* scanned by the ultrasonic transducer, wherein the physical sensor is *independent* from the ultransonic transducer; and a control system coupled to the ultrasound probe and configured to control *power* modes of the ultrasound probe based on feedback from the *physical sensor*."

Emory fails to teach or suggest "an ultrasound probe, comprising an ultrasonic transducer; and a physical sensor adapted to sense *engagement* with a subject to be scanned by the ultrasonic transducer, wherein the physical sensor is *independent* from the ultransonic transducer," as recited by claim 1. On a preliminary note, the Appellants submit that the Examiner is not giving proper weight to the two independent elements in the claim, e.g., physical sensor and ultrasonic transducer. Clearly, the claim language sets forth an independent relationship between these two components, whereas Emory only has one integral element. Emory uses the ultrasound transducer 56 for all functions, thereby clearly omitting an independent physical sensor. Emory specifically discloses a principle of operation based on different types of reflected ultrasound signals corresponding to either a soft tissue or air, which signal representative of air is used to deactivate the ultrasound probe. In other words, Emory is only used to deactivate an already running ultrasound probe. It does not detect engagement with a subject as recited by claim 1. Moreover, given that Emory uses the ultrasound signal itself as a detection mechanism, it does not utilize an independent physical sensor to sense engagement with a subject. Again, Emory discloses only deactivation of an operating ultrasound system to prevent overheating. Specifically, Emory discloses:

> When the transducer 56 is not coupled to the tissue 60 but a nonabsorbing medium such as air and the transducer elements 106 are still excited, the majority of the energy that was coupled into the patient is reflected back towards the ultrasound transducer 56 from the lens 102/air interface to be reabsorbed. Again some of the energy is dissipated in the lens 102, matching layers 104 and 108, backing 112 and PZT element 110 causing further heating.
>
> Low energy coupled into air implies that the majority of the energy is absorbed in the transducer. The pulse-echo response also provides information about the reflected pulse from the lens/air interface. …
>
> Accordingly, a system and method in accordance with the present invention detects when the ultrasound transducer is coupling energy into soft tissue 60 or into the air and deactivates the probe when the probe is coupling energy into air. In so doing, the thermal performance of the transducer improves allowing an increase in the duration and level of excitation voltage used from the pulse generator 52. …

> FIG. 3a shows the initial pulse echo response from a lens that is coupled into a fat layer. … The lens impedance is assumed to be 1.5 MRayls and the fat layer has an impedance of 1.45 MRayls. If the same array element is coupled into air, the pulse-echo response changes significantly as shown in FIG. 3b. The pulse rings more because of continuous reflections off of the lens/air interface 102 (FIG. 2). The pulse amplitude has also dramatically changed. The significant differences in the pulse response allows specific time windows and spectral based algorithms to be used to detect when the transducer is coupling energy into air.

Emory, col. 3, lines 35-47 and 51-57; col. 4 lines 9-10 and 14-22 (emphasis added). Clearly, the foregoing passage describes a principle of operation requiring use of the ultrasound signals, rather than any other signals, to deactivate the ultrasound probe when the probe is away from the soft tissue. Emery analyzes the nature of the pulse echo to determine whether the transducer is transmitting into air or into tissue. As discussed in detail below, it would be improper to modify the teaching of Emory to change this principle of operation as suggested by the Examiner. *See* M.P.E.P.§2143.01(VI).

In addition, Emory discloses additional "control mechanisms may be added to the system or probe to determine whether a probe is in use." Emory, col. 5, lines 59-60. The disclosed "sensors may include: (1) motion detectors (2) optical emitter/detector pairs (3) thermal sensors." Emory, col. 5, line 67-col. 6, line 3 (emphasis added). For example, Emory discloses that the "motion detector would simply detect movement of the probe, which primarily occurs during scanning." Emory, col. 6, lines 4-5 (emphasis added). Clearly, none of these sensors is "adapted to sense engagement with a subject to be scanned by the ultrasonic transducer," as recited by claim 1. Motion is clearly not the same as engagement. These additional sensors are concerned with sensing use of an already operating ultrasound probe. In view of these passages, among others, Emory cannot support a *prima facie* case of obviousness of indepednent claim 1 and its dependent claims. Furthermore, the secondary references do not obviate the deficiencies of Emory.

***Independent Claim 9***

Independent claim 9 recites "*physically* sensing *engagement* of an ultrasound module with a subject using a *non*-ultrasonic sensor; and switching power modes of the ultrasound module based on the sensed *engagement*." For substantially the same reasons as discussed above with reference to claim 1, Emory, taken alone or in hypothetical combination with the secondary references, cannot support a *prima facie* case of obviousness of claim 9 and its dependnet claims.

***Independent Claim 15***

Independent claim 15 recites "an ultrasonic transducer configured to scan a subject; and a *non*-ultrasonic sensing element configured to detect physical *proximity* of the hand holdable ultrasound probe relative to the subject; … the control system is configured to switch the ultrasound probe between a plurality of power modes based on feedback from the sensing element." For substantially the same reasons as discussed above with reference to claim 1, Emory, taken alone or in hypothetical combination with the secondary references, cannot support a *prima facie* case of obviousness of claim 15 and its dependnet claims. The Appellants also stress that detecting physical *proximity*, as recited above, is clearly different than detecting *motion*.

***Independent Claim 18***

Independent claim 18 recites "providing an ultrasound unit having an ultrasound transducer to scan a subject and a physical sensor to *non*-ultrasonically detect *proximity* of a subject relative to the ultrasound unit; and providing a control system to change power levels of the ultrasound unit based on the feedback from the physical sensor." For substantially the same reasons as discussed above with reference to claim 1, Emory, taken alone or in hypothetical combination with the secondary references, cannot support a *prima facie* case of obviousness of claim 18 and its dependnet claims.

***Independent Claim 23***

Independent claim 23 recites "means for sensing *non*-ultrasonic signals to detect *proximity* of an ultrasound module relative to a subject to be scanned by ultrasonic transducers of the ultrasound module; and means for switching power modes of the ultrasound probe based on *proximity* feedback from the means for sensing." For substantially the same reasons as discussed above with reference to claim 1, Emory, taken alone or in hypothetical combination with the secondary references, cannot support a *prima facie* case of obviousness of claim 23 and its dependnet claims.

Appellants respectfully note that claim 23, which was rejected under 35 U.S.C. § 103 in view of the cited reference, includes means-plus-function language, as set forth in 35 U.S.C. § 112, paragraph 6, *and should be examined in accordance with this body of law*. As may be appreciated, with respect to 35 U.S.C. § 112, paragraph 6, an Examiner "may not disregard the structure disclosed in the specification corresponding to such language when rendering a patentability determination." *In re Donaldson Co.*, 29 U.S.P.Q.2d 1845 (Fed. Cir. 1994); *see also* Manual of Patent Examining Procedure § 2181. Appellants note that proper interpretation of this claim must be performed with reference to the structure provided in the specification. Particularly, with regard to the "means for sensing non-ultrasonic signals to detect proximity of an ultrasound module relative to a subject to be scanned by ultrasonic transducers of the ultrasound module" recitation of claim 23, Appellants' specification discloses physical sensors (*e.g.*, 20), 81, 82) for performing the recited function. *See, e.g.*, Application, FIGS. 1 and 3, paragraphs [0011], [0012], [0015], [0017], [0031], and [0032]. With regard to the "means for switching power modes of the ultrasound probe based on proximity feedback from the means for sensing" recitation of claim 23, Appellants' specification discloses a control system (*e.g.*, 14) and a control process (*e.g.*, 86) for performing the recited function. *See, e.g.*, Application, FIGS. 1 and 3, paragraphs [0017], [0031], and [0032]. For example, the specification discloses:

> [0015] In the ultrasound probe 12, the physical sensors 20 detect when the ultrasound probe 12 is in contact, close proximity, or generally approaching the subject to be ultrasonically scanned by the ultrasonic transducer array 18. For example, the physical sensors 20 may sense temperature, pressure, distance, or other physical characteristics of the subject 16, such that the ultrasound probe 12 can be powered up from a low power mode to an operational power mode for performing an ultrasonic scan upon engaging the subject 16. The transducer array 18 is adapted to contact with subject 16, such that an ultrasonic scan may be performed to analyze internal features of the subject 16.
>
> [0017] In ultrasound control unit 14, the control unit 32 is coupled to a power mode processor 30, which is communicatively coupled to physical sensors 20. Similarly, the power mode processor 30 may be located within the ultrasound probe 12. As discussed above, the physical sensors 20 detect various physical characteristics, such as heat transfer, contact pressure, proximity distance, and other characteristics of the subject 16. These sensed physical characteristics are then transmitted to the power mode processor 30, which controls the power mode of the ultrasound probe 12 via the control unit 32. For example, the power mode processor 30 and control unit 32 may comprise a plurality of power modes, such as a low power mode and an operational power mode, for the ultrasound probe12. If the physical sensors 20 detect engagement or approaching engagement of the ultrasound probe 12 with the subject 16, then the power mode may be shifted from the low power mode to the operational power mode to facilitate ultrasonic scanning of the subject 16.
>
> [0026] In the illustrated embodiment, the temperature sensing element 81 and the pressure sensing element 82 are disposed at outer peripheral portions of the front face or lens 80 of the ultrasound probe 58. For example, the sensing elements 81 and 82 may be embedded into the lens 80 or located next to the lens 80. Although not illustrated, other embodiments may include various other types of physical sensors, such as distance or proximity sensors, motion sensors, and so forth. As discussed above, these physical sensors, e.g., 81 and 82, facilitate detection of the subject 16, such that the ultrasound system 10 can power up or increase power modes when the ultrasound probe 58 is in a position to begin ultrasound scanning.

Appellants respectfully stress that the cited reference fails to teach or suggest such structure. Accordingly, the Office Action failed to establish a *prima facie* case of unpatentability *in accordance with* the relevant statutory and precedential authority

outlined above. Appellants respectfully submit that independent claim 23 is patentable over the cited reference.

***Improper Combination - Lack of Objective Evidence of Reason to Modify Emery***

In addition, the Examiner has not shown the requisite motivation or suggestion to modify or combine the cited references to reach the present claims. As summarized above, the Examiner must provide objective evidence, rather than subjective belief and unknown authority, of the requisite motivation or suggestion to combine or modify the cited references. *In re Lee*, 61 U.S.P.Q.2d. 1430 (Fed. Cir. 2002). In the present rejection, the Examiner combined the cited references based on the *conclusory and subjective statement* that:

> Although Emery does not explicitly state that these independent physical sensors detect 'engagement with the subject' as called for in the claim to the degree of inherency necessary for anticipation (since motion might conceivably including handling motion by the operator, tissue reflectivity might indicate proximation prior to engagement, thermal might pertain to self-heating due to activation and so on), it would have been inherently obvious to use at least the tissue reflectivity sensor to sense active *engagement* with the subject. In effect this is tantamount to the distance (proximity) sensor which applicants list in specification para [0015] as a category of physical sensor. Final Office Action, page 3 (emphasis added).

However, the Examiner did not provide any suggestion or motivation for the hypothetical modification of Emery. Again, Emery is clearly analyzing the pulse characteristics to determine whether the transducer 56 is transmitting into air or into tissue. *See* Emery, col. 3, lines 35-55; col. 4, lines 8-46. The motion detectors, optical emitter/detector pairs, and the thermal sensors are used to detect "when the probe is in use." Emery, col. 5, lines 66-67; col. 6, lines 1-12. For example, Emery discloses that the "motion detector would simply detect movement in the probe, which primarily occurs during scanning." Emery, col. 6, lines 4-5. Emery further discloses that the "optical emitter/detector pair would sense the amount of light reflected by the tissue." Emery does not teach or suggest that any of these would or could be used to detect proximity or engagement as generally

recited by the independent claims. In view of the complete lack of support for this modification, the Appellants respectfully stress that a *prima facie* case of obviousness has not been made. Therefore, the Appellants respectfully request withdrawal of the foregoing rejection.

***Improper Combination – Emery teaches away from proposed modification***

In addition to the complete lack of objective evidence, the Appellants stress that Emery teaches away from the proposed modification. *See In re Grasselli*, 713 F.2d 731 at 743. Specifically, Emery teaches away from a physical sensor to detect proximity or engagement, as generally recited by the independent claims. As discussed in detail above, Emery contrastingly teaches a testing procedure in which the pulse shape of the transducer 56 is analyzed to determine whether the transducer is transmitting into air or into tissue. *See* Emery, FIGS. 3A and 3B; col. 3, lines 35-55; col. 4, lines 25-43. It would be completely against the clear teaching of Emery to change the testing process (see FIG. 4) from one based on the different pulse signals (see FIGS. 3A and 3B) originating from the transducer 56 to one based on detection of physical proximity or engagement. Moreover, as noted above, the motion detectors, optical emitter/detector pairs, and the thermal sensors are used to detect "when the probe is in use" rather than physical proximity or engagement. Emery, col. 5, lines 66-67; col. 6, lines 1-12. For example, Emery discloses that the "motion detector would simply detect movement in the probe, which primarily occurs during scanning." Emery, col. 6, lines 4-5. Emery further discloses that the "optical emitter/detector pair would sense the amount of light reflected by the tissue." Emery does not teach or suggest that any of these would or could be used to detect proximity or engagement as generally recited by the independent claims. For at least this reason, among others, the proposed combination is improper and must be withdrawn.

***Improper Combination – Emery teaches a principle of operation that would change if modified in the manner proposed by the Examiner***

For similar reasons, Emery teaches a principle of operation that would change if hypothetically modified as suggested by the Examiner. As summarized above, a proposed modification or combination of references is entirely improper and insufficient to support a *prima facie* case of obviousness, where the proposed modification or combination would change the principle of operation of the cited reference or render the cited reference unsatisfactory for its intended purpose.

Emory teaches a principle of operation of analyzing the pulse shape to determine whether the transducer 56 is transmitting into air or into tissue. *See* Emery, FIGS. 3A and 3B; col. 3, lines 35-55; col. 4, lines 25-43. For example, FIG. 3A shows the initial pulse-echo response from a lens that is coupled into a fat layer, whereas FIG. 3B shows that the initial pulse-echo response changes significantly if the same array element is coupled into air. See Emery, col. 2, lines 17-21; col. 4, lines 8-43. Thus, the principle of operation of Emery requires analysis and control based on characteristics of the pulse-echo response. The Examiner has proposed an unsupported modification in which the proximity or engagement would be detected. However, such proximity or engagement detection would render the pulse-echo analysis and control technique of Emery inoperable for its intended purpose. In other words, the proposed modification would completely change the entire focus and principle of operation of Emery.

For at least these reasons, among others, the Appellants respectfully request withdrawal of the foregoing combination and the corresponding rejections under 35 U.S.C.§103.

**Second Ground of Rejection:**

The Examiner improperly rejected claims 4 and 19 under 35 U.S.C. § 103(a) as unpatentable over Emery in view of Chiang et al. (U.S. Patent No. 5,957,846, hereinafter,

"Chiang"). Because this rejection is clearly and directly contrary to previous binding decisions of the Board, as well as the binding precedent of the Federal Circuit, Appellants respectfully traverse this rejection. The Appellants note that claim 4 depends from independent claim 1, while claim 19 depends from independent claim 18. As discussed above with reference to the first ground of rejection, Emery fails to teach or suggest a number of features recited by independent claims 1 and 18. The Examiner cited Chiang solely for its alleged disclosure of a beamformer in a hand holdable body. *See* Final Office Action, page 3. However, Chiang does not obviate the deficiencies of Emery with regard to independent claims 1 and 18. As a result, the cited references, taken alone or in hypothetical combination with one another, cannot support a *prima facie* case of obviousness of claims 4 and 19.

**Third Ground of Rejection:**

The Examiner improperly rejected claims 5-6, 20, and 24 under 35 U.S.C.§103(a) as unpatentable over Emery in view of Akisada et al. (U.S. Patent No. 6,183,426, hereinafter, "Akisada"). Because this rejection is clearly and directly contrary to previous binding decisions of the Board, as well as the binding precedent of the Federal Circuit, Appellants respectfully traverse this rejection. The Appellants note that claims 5 and 6 depend from independent claim 1, claim 20 depends from independent claim 18, and claim 24 depends from independent claim 23. As discussed above with reference to the first ground of rejection, Emery fails to teach or suggest a number of features recited by independent claims 1, 18, and 23. The Examiner cited Akisada solely for its alleged disclosure of a pressure sensor. *See* Final Office Action, page 4. However, Akisada does not obviate the deficiencies of Emery with regard to independent claims 1, 18, and 23. As a result, the cited references, taken alone or in hypothetical combination with one another, cannot support a *prima facie* case of obviousness of claims 5-6, 20, and 24.

The Appellants stress the cited references teach away from one another and, therefore, are not properly combinable. *See In re Grasselli*, 713 F.2d 731 at 743. Specifically, Emery teaches away from a pressure sensor. As discussed in detail above,

Emery contrastingly teaches a testing procedure in which the pulse shape of the transducer 56 is analyzed to determine whether the transducer is transmitting into air or into tissue. *See* Emery, FIGS. 3A and 3B; col. 3, lines 35-55; col. 4, lines 25-43. It would be completely against the clear teaching of Emery to change the testing process (see FIG. 4) from one based on the different pulse signals (see FIGS. 3A and 3B) originating from the transducer 56 to one based on a pressure sensor. For at least this reason, among others, the proposed combination is improper and must be withdrawn.

In addition, the cited references teach contrastingly different intended purposes and principles of operation, which would change if the cited references were hypothetically combined as suggested by the Examiner. As summarized above, a proposed modification or combination of references is entirely improper and insufficient to support a *prima facie* case of obviousness, where the proposed modification or combination would change the principle of operation of the cited reference or render the cited reference unsatisfactory for its intended purpose.

Emory teaches a principle of operation of analyzing the pulse shape to determine whether the transducer 56 is transmitting into air or into tissue. *See* Emery, FIGS. 3A and 3B; col. 3, lines 35-55; col. 4, lines 25-43. For example, FIG. 3A shows the initial pulse-echo response from a lens that is coupled into a fat layer, whereas FIG. 3B shows that the initial pulse-echo response changes significantly if the same array element is coupled into air. See Emery, col. 2, lines 17-21; col. 4, lines 8-43. Thus, the principle of operation of Emery requires analysis and control based on characteristics of the pulse-echo response. In contrast, Akisada teaches a principle of operation of using "a load detection circuit which monitors whether the vibration element is loaded such as by contact with the skin." Akisada, Abstract. In view of these contrasting different principles of operation, the Examiner's proposed combination of the primary and secondary references is absolutely improper and cannot stand.

For at least these reasons, among others, the Appellants respectfully request withdrawal of the foregoing combination and the corresponding rejections under 35 U.S.C.§103.

**Fourth Ground of Rejection:**

The Examiner improperly rejected claims 8, 10-11, 13 and 16 under 35 U.S.C.§ 103(a) as unpatentable over Emery in view of Whitney et al. (U.S. Patent No. 5,396,891, hereinafter, "Whitney"). Because this rejection is clearly and directly contrary to previous binding decisions of the Board, as well as the binding precedent of the Federal Circuit, Appellants respectfully traverse this rejection. The Appellants note that claim 8 depends from independent claim 1, claims 10, 11, and 13 depend from independent claim 9, and claim 16 depends from independent claim 15. As discussed above with reference to the first ground of rejection, Emery fails to teach or suggest a number of features recited by independent claims 1, 9, and 15. The Examiner cited Whitney solely for its alleged disclosure of manual switch. *See* Final Office Action, page 4. However, Whitney does not obviate the deficiencies of Emery with regard to independent claims 1, 9, and 15. As a result, the cited references, taken alone or in hypothetical combination with one another, cannot support a *prima facie* case of obviousness of claims 8, 10-11, 13 and 16.

In addition, the Examiner has not shown the requisite motivation or suggestion to modify or combine the cited references to reach the present claims. As summarized above, the Examiner must provide objective evidence, rather than subjective belief and unknown authority, of the requisite motivation or suggestion to combine or modify the cited references. *In re Lee*, 61 U.S.P.Q.2d. 1430 (Fed. Cir. 2002). In the present rejection, the Examiner combined the cited references based on the *conclusory and subjective statement* that "[c]laims 8, 10-11, 13, 16 are rejected under 35 U.S.C.§ 103(a) as being unpatentable over Emery as applied to claim 1 above, and further in view of Whitney et al (US5396891, of record) since whereas the former does not entertain such for proximity sensing, it would have been obvious in view of the latter to use a manually

operable switch to sense physical contact as a form of coupling engagement." Final Office Action, page 4. In view of the complete lack of support for this combination, the Appellants respectfully stress that a *prima facie* case of obviousness has not been made. Therefore, the Appellants respectfully request withdrawal of the foregoing rejection.

In addition to the complete lack of objective evidence, the Appellants stress the cited references teach away from one another and, therefore, are not properly combinable. *See In re Grasselli*, 713 F.2d 731 at 743. Specifically, Emery teaches away from a manual switch, or pressure sensor, or sensing physical contact, or a combination thereof. As discussed in detail above, Emery contrastingly teaches a testing procedure in which the pulse shape of the transducer 56 is analyzed to determine whether the transducer is transmitting into air or into tissue. *See* Emery, FIGS. 3A and 3B; col. 3, lines 35-55; col. 4, lines 25-43. It would be completely against the clear teaching of Emery to change the testing process (see FIG. 4) from one based on the different pulse signals (see FIGS. 3A and 3B) originating from the transducer 56 to one based on a manual switch, or a pressure sensor, or sensing physical contact. For at least this reason, among others, the proposed combination is improper and must be withdrawn.

For similar reasons, the cited references teach contrastingly different intended purposes and principles of operation, which would change if the cited references were hypothetically combined as suggested by the Examiner. As summarized above, a proposed modification or combination of references is entirely improper and insufficient to support a *prima facie* case of obviousness, where the proposed modification or combination would change the principle of operation of the cited reference or render the cited reference unsatisfactory for its intended purpose.

Emory teaches a principle of operation of analyzing the pulse shape to determine whether the transducer 56 is transmitting into air or into tissue. *See* Emery, FIGS. 3A and 3B; col. 3, lines 35-55; col. 4, lines 25-43. For example, FIG. 3A shows the initial pulse-echo response from a lens that is coupled into a fat layer, whereas FIG. 3B shows

that the initial pulse-echo response changes significantly if the same array element is coupled into air. See Emery, col. 2, lines 17-21; col. 4, lines 8-43. Thus, the principle of operation of Emery requires analysis and control based on characteristics of the pulse-echo response. In contrast, Whitney teaches a principle of operation of using "a plurality of contact buttons projecting in a common direction, the buttons being axially displaceable and fitted with an engagement sensing arrangement for determining contact with the body part such that operation of the device may be inhibited until proper contact is made." Whitney, Abstract. In view of these contrasting different principles of operation, the Examiner's proposed combination of the primary and secondary references is absolutely improper and cannot stand.

For at least these reasons, among others, the Appellants respectfully request withdrawal of the foregoing combination and the corresponding rejections under 35 U.S.C.§103.

**Conclusion**

In view of the above remarks, Appellants respectfully submit that the Examiner has provided no supportable position or evidence that would justify the present improper rejections of the present claims. Consequently, Appellants respectfully submit that all pending claims are in condition for allowance. However, if the Examiner or Board wishes to resolve any other issues by way of a telephone conference, the Examiner or Board is kindly invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

Date: February 19, 2010

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## 8. CLAIMS APPENDIX

### Listing of Claims:

1. An ultrasound system, comprising:

an ultrasound probe, comprising

an ultrasonic transducer; and

a physical sensor adapted to sense engagement with a subject to be scanned by the ultrasonic transducer, wherein the physical sensor is independent from the ultransonic transducer; and

a control system coupled to the ultrasound probe and configured to control power modes of the ultrasound probe based on feedback from the physical sensor.

3. The system of claim 1, wherein the ultrasound probe comprises a hand holdable body.

4. The system of claim 3, wherein the hand holdable body comprises at least a portion of a beamformer.

5. The system of claim 1, wherein the physical sensor comprises a pressure sensor configured to detect a contact pressure with the subject.

6. The system of claim 5, wherein the pressure sensor comprises a piezoelectric sensor element.

7. The system of claim 1, wherein the physical sensor comprises a temperature sensor configured to detect thermal proximity with the subject.

8. The system of claim 1, wherein the physical sensor comprises a manual power switch.

9. A method for controlling heat in an ultrasound system, the method comprising:

physically sensing engagement of an ultrasound module with a subject using a non-ultrasonic sensor; and

switching power modes of the ultrasound module based on the sensed engagement.

10. The method of claim 9, comprising:

manually switching the power modes at a handheld unit of the ultrasound module.

11. The method of claim 9, wherein physically sensing engagement comprises detecting a contact pressure with the subject.

12. The method of claim 9, wherein physically sensing engagement comprises detecting thermal proximity of the subject.

13. The method of claim 9, wherein physically sensing engagement comprises detecting physical contact of a hand holdable probe of the ultrasound module with the subject.

14. The method of claim 9, wherein switching power modes comprises increasing power of the ultrasound module upon sensing engagement with the subject to enable ultrasonic scanning of the subject.

15. An ultrasound system, comprising:

a hand holdable ultrasound probe, comprising:

an ultrasonic transducer configured to scan a subject; and

a non-ultrasonic sensing element configured to detect physical proximity of the hand holdable ultrasound probe relative to the subject; and

a control system coupled to the hand holdable ultrasound probe, wherein the control system is configured to switch the ultrasound probe between a plurality of power modes based on feedback from the sensing element.

16. The system of claim 15, wherein the sensing element comprises a pressure sensor configured to detect a contact pressure between the hand holdable ultrasound probe and the subject.

17. The system of claim 15, wherein the sensing element comprises a temperature sensor configured to detect a temperature differential between the hand holdable ultrasound probe and the subject.

18. A method of manufacture, comprising:

providing an ultrasound unit having an ultrasound transducer to scan a subject and a physical sensor to non-ultrasonically detect proximity of a subject relative to the ultrasound unit; and

providing a control system to change power levels of the ultrasound unit based on the feedback from the physical sensor.

19. The method of claim 18, wherein providing the ultrasound unit comprises providing a hand holdable body having the ultrasound transducer, the physical sensor, and a beamformer coupled to the ultrasound transducer.

20. The method of claim 18, wherein providing the ultrasound unit comprises disposing a pressure sensor on the hand holdable body of the ultrasound unit.

21. The method of claim 18, wherein providing the ultrasound unit comprises disposing a temperature sensor on the hand holdable body of the ultrasound unit.

23. An ultrasound system, comprising:

means for sensing non-ultrasonic signals to detect proximity of an ultrasound module relative to a subject to be scanned by ultrasonic transducers of the ultrasound module; and

means for switching power modes of the ultrasound probe based on proximity feedback from the means for sensing.

24. The system of claim 1, wherein the physical sensor comprises a pressure sensor and a temperature sensor.

9. **EVIDENCE APPENDIX**

none

10. **RELATED PROCEEDINGS APPENDIX**

none